NIST TEL MRA Program

Scopes of the EU and UK Regulatory Schemes Covered under the TEL MRAs

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The CAB's ISO/IEC 17065 Scope of Accreditation – Mandatory and Optional Content

Version 2.0 (September 25, 2024)

Introduction:

This document contains the scopes of the EU and UK regulatory schemes covered under the US-EU and US-UK TEL MRAs. The applicable regulations, supplementary legislation, categories of products (legal description from legislation), and essential requirements currently activated under the applicable legislation(s) are included.

US CABs must have access to and be knowledgeable about the legislation and supplementary legislation listed in this document.

US CABs seeking to obtain EU Notified Body status and UK Approved Body status shall obtain ISO/IEC 17065 accreditation for the applicable legislation, categories of products, and essential requirements for which the CAB is seeking to be notified/designated.

The Scope of Accreditation shall contain the information noted in the tables below.

- Information show in green text is optional. CABs have the option to include all the details, or to simplify the presentation of information to just the mandatory elements.
- The format may differ, and additional information may be included in the CAB's Scope of Accreditation.

The categories of products and/or specific products are identified in the legislation or supplementary legislation. No other categories of products can be added other than those covered by the legislation.

For NBs that select Option 3 (a Scope of Accreditation that covers <u>all products</u> in the applicable legislation), the Option 3 statement can apply to all essential requirements, but it is then understood that applicable essential requirements are only valid for and are limited to the category of products noted in the legal description (listed below). However, please note that for the EU Notified Bodies, regarding RED Articles 3.3g and 3.4, NIST may need to specify the <u>specific products</u> as noted below directly in NANDO, even if the specific equipment is not specified to this level on the Scope of Accreditation.

The UK RER does not have the same list of activated essential requirements as the EU RED. Specifically, the EU activated RED Articles 3.3 d/e/f, RED Article 3.3g (mobile phones/Galileo) and RED Article 3.4 (common charger) *after Brexit*, and the UK **did not** activate the equivalent essential requirements for the UK RER.

Questions related to this document can be directed to the NIST TEL MRA Program: mra@nist.gov (Attn: Ramona Saar, Program Manager)

EU Radio Equipment Directive 2014/53/EU (RED)

EU Radio Equipment Directive 2014/53/EU (RED) *

Annex III (Module B : EU Type Examination)

Annex III (Module B : EU Type Examination)		
Category of Products **	RED Essential Requirements (with brief descriptor)	Applicable Supplementary Legislation/Notes/ Exclusions
Option 1: Use legal description Radio equipment (an electrical or electronic product, which intentionally emits and/or receives radio waves for the	RED Article 3.1a (Safety & health) RED Article 3.1b	None
purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as	(EMC) RED Article 3.2	
antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination)	(Efficient/effective use of spectrum)	
Option 2:		
Include list of types of equipment.		
Option 3: If the NB covers all equipment, include a statement such as:		
All radio equipment (excluding equipment as stipulated in Article 1.2 and Article 1.3 of the RED).		
Option 1:	RED Article 3.3d (Cybersecurity:	Commission Delegated Regulation
Internet-connected radio equipment	Protection of the network)	(EU) 2022/30 of 29 October 2021
Option 2: If the NB covers all equipment, include a statement such as:		
All applicable radio equipment under RED Article 3.3d		

Option 1	RED Article 3.3e (Cybersecurity: Protection of	Commission Delegated Regulation (EU) 2022/30 of 29
The following radio equipment, if that radio equipment is capable of processing, within the meaning of Article 4(2) of Regulation (EU) 2016/679, personal data, as defined in Article 4(1) of Regulation (EU) 2016/679, or traffic data and location data, as defined in Article 2, points (b) and (c), of Directive 2002/58/EC:	personal data and privacy)	October 2021
(a) internet-connected radio equipment, other than the equipment referred to in points (b), (c) or (d);		
(b) radio equipment designed or intended exclusively for childcare		
(c) radio equipment covered by Directive 2009/48/EC		
(d) radio equipment designed or intended, whether exclusively or not exclusively, to be worn on, strapped to, or hung from any of the following:(i) any part of the human body, including the head, neck, trunk, arms, hands, legs and feet; (ii) any clothing, including headwear, hand wear and footwear, which is worn by human beings.		
Option 2: If the NB covers all equipment, include a statement such as:		
All applicable radio equipment under RED Article 3.3e		
Option 1:	RED Article 3.3f (Cybersecurity: protection from	Commission Delegated Regulation (EU) 2022/30 of 29
Any internet-connected radio equipment, if that equipment enables the holder or user to transfer money, monetary value or virtual currency as defined in Article 2, point (d), of Directive (EU) 2019/713 ¹	financial fraud)	October 2021.
Option 2: If the NB covers all equipment, include a statement such as:		
All applicable radio equipment under RED Article 3.3f		

¹ Directive (EU) 2019/713 of the European Parliament and of the Council of 17 April 2019 on combating fraud and counterfeiting of non-cash means of payment and replacing Council Framework Decision 2001/413/JHA

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Radio equipment covered by the regional arrangement	RED Article 3.3g	Commission Decision
concerning the radiotelephone service on inland waterways	(Access to emergency	2000/637/EC of 22
	services – legacy	September 2000
	R&TTED decisions)	
Avalanche beacons	RED Article 3.3g	Commission Decision
	(Access to emergency	2001/148/EC of 21
	services– legacy	February 2001
	R&TTED decisions)	
Radio equipment intended to participate in the Automatic	RED Article 3.3g	Commission Decision
Identification System (AIS).	(Access to emergency	2005/53/EC of 25
	services-legacy	January 2005
	R&TTED decisions)	
Cospas-Sarsat locator beacons	RED Article 3.3g	Commission Decision
	(Access to emergency	2005/631/EC of 29
	services-legacy	August 2005
	R&TTED decisions)	
Marine radio communication equipment which is intended	RED Article 3.3g	Commission Decision
to be used on non-SOLAS vessels and to participate in the	(Access to emergency	2013/638/EC of 12
Global Maritime Distress and Safety System (GMDSS)	services-legacy	August 2013
	R&TTED decisions)	
Hand-held mobile telephones with features similar to those	RED Article 3.3g	Commission
of a computer in terms of capability to treat and store data	(Access to emergency	Delegated Regulation
or a computer in terms of capability to treat and store data	services – mobile	(EU) 2019/320 of 12
	phones)	December 2018
	priories	December 2010
Handheld mobile phones, tablets, digital cameras,	RED Article 3.4	None.
headphones, headsets, handheld videogame consoles,	(Common charger)	NOTIC.
portable speakers, E-readers, keyboards, mice, portable	(Common charger)	Note: See Annex Ia
navigation systems, earbuds, laptops		(Directive (EU)
inavigation systems, earbuus, iaptops		
		2022/2380)

^{*} EU Radio Equipment Directive 2014/53/EU (RED): Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014, amended by Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018, Article 138, amended by Directive (EU) 2022/2380 of the European Parliament and of the Council of 23 November 2022

^{**} Excluding equipment as stipulated in Article 1.2 and Article 1.3 of the EU Radio Equipment Directive 2014/53/EU

UK Radio Equipment Regulations 2017 (S.I. 2017/1206)

UK Radio Equipment Regulations 2017 (S.I. 2017/1206) * Schedule 3, Module B (Type Examination)

https://www.legislation.gov.uk/uksi/2017/1206/contents

Category of Products **	Radio Equipment Regulations Essential Requirements (with brief descriptor)	Applicable Supplementary Legislation/Notes/ Exclusions
Option 1: Include legal description: Radio equipment (an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination) Option 2: Include list of types of equipment. Option 3: If the UK AB covers all equipment, include a statement such as: Includes all radio equipment except radio equipment stipulated in regulation 3.(2) and Schedule 1 of the UK RER.	Regulation 6.(1)(a) (health and safety) Regulation 6.(1)(b) (EMC) Regulation 6.2 (Efficient/effective use of spectrum)	None
Radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways	Regulation 6A (2)(g) (Access to emergency services)	Commission Decision 2000/637/EC of 22 September 2000 legislation.gov.uk.
Avalanche beacons	Regulation 6A (2)(g) (Access to emergency services)	Commission Decision 2001/148/EC of 21 February 2001 legislation.gov.uk.
Radio equipment intended to participate in the Automatic Identification System (AIS).	Regulation 6A (2)(g) (Access to emergency services)	Commission Decision 2005/53/EC of 25 January 2005 as referenced on legislation.gov.uk.

Cospas-Sarsat locator beacons	Regulation 6A (2)(g)	Commission Decision
	(Access to emergency	2005/631/EC of 29
	services)	August 2005 as
		referenced on
		legislation.gov.uk.
Marine radio communication equipment which is intended	Regulation 6A (2)(g)	Commission Decision
to be used on non-SOLAS vessels and to participate in the	(Access to emergency	2013/638/EC of 12
Global Maritime Distress and Safety System (GMDSS)	services)	August 2013 as
		referenced on
		legislation.gov.uk

^{*} The Radio Equipment Regulations 2017 (S.I. 2017/1206) as modified by:

- S.I. 2023/328, The Radio Equipment (Amendment) (Northern Ireland) Regulations 2023
- S.I. 2022/1393, The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022
- S.I. 2021/1273, The Product Safety and Metrology etc. (Amendment) Regulations 2021
- S.I. 2021/730, The Conformity Assessment (Mutual Recognition Agreements) and Weights and Measures (Intoxicating Liquor) (Amendment) Regulations 2021
- S.I. 2020/1460, The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020
- S.I. 2020/1112, The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020
- S.I. 2020/852, The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020
- S.I. 2020/676, The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020
- European Union (Future Relationship) Act 2020 c.29
- S.I. 2019/1246, The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019
- S.I. 2019/696, The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
- S.I. 2018/389, The Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018

Above list correct as of 8/12/2024 with reference to https://www.legislation.gov.uk/changes/affected/uksi/2017/1206

** Excluding equipment as stipulated in regulation 3.(2) and Schedule 1 of the Radio Equipment Regulations 2017 (S.I. 2017/1206)

EU EMC Directive 2014/30/EU (EMCD)

EU EMC Directive 2014/30/EU (EMCD) * Annex III – Part A (Module B: EU-type Examination)

Category of Products **	EMCD Essential Requirements (with brief descriptor)	Applicable Supplementary Legislation/Notes/ Exclusions
Option 1: Include legal description	Annex I, Item 1 (a) (the electromagnetic	None
Electric and electronic apparatus ('apparatus' means any	disturbance	
finished appliance or combination thereof made available on the market as a single functional unit, intended for the	generated)	
end-user and liable to generate electromagnetic	Annex I, Item 1 (b)	
disturbance, or the performance of which is liable to be	(the level of	
affected by such disturbance)	immunity to electromagnetic	
Option 2: Include a list of electric and electronic apparatus.	disturbance)	
Option 3: If the NB covers all apparatus covered under the		
EMCD, the NB can include a statement such as: All electric		
and electronic apparatus covered under the EMCD		
excluding what is stipulated in EMCD Article 2.2 and		
excluding fixed installations		

^{*} EMC Directive 2014/30/EU (EMCD): Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014, amended by Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018, Article 137

^{**} Excluding equipment as stipulated in in Article 2.2 of the EU EMC Directive 2014/30/EU and fixed installations

UK Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091)

Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091) - EMCR Schedule 3, Part 1, Module B (Type Examination)

https://www.legislation.gov.uk/uksi/2016/1091/contents

Radio Equipment

Applicable

Radio Equipment	Applicable
Regulations Essential	Supplementary
Requirements (with	Legislation/Notes/Ex
brief descriptor)	clusions
Schedule I, Item 1.(a)	None
(the electromagnetic	
disturbance	
generated)	
Schedule I, Item 1.(b)	
(the level of	
immunity to	
_	
disturbance)	
_	Regulations Essential Requirements (with brief descriptor) Schedule I, Item 1.(a) (the electromagnetic disturbance generated) Schedule I, Item 1.(b) (the level of

- * The Electromagnetic Compatibility Regulations 2016 (S.I. 2016/1091) as modified by:
 - S.I. 2022/1393, The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022
 - S.I. 2021/1273, The Product Safety and Metrology etc. (Amendment) Regulations 2021
 - S.I. 2021/730, The Conformity Assessment (Mutual Recognition Agreements) and Weights and Measures (Intoxicating Liquor) (Amendment) Regulations 2021
 - S.I. 2020/1460, The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020
 - S.I. 2020/1112, The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020
 - S.I. 2020/852, The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020

Category of Products **

- S.I. 2020/676, The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020
- European Union (Future Relationship) Act 2020 c.29
- S.I. 2019/1246, The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019
- S.I. 2019/696, The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
- S.I. 2017/1206, The Radio Equipment Regulations 2017

Above list correct as of 1/18/2023 with reference to https://www.legislation.gov.uk/changes/affected/all/2016/1091

** Excluding equipment as stipulated in regulations 3.(2), 3.(3) and 3.(4) of the UK Electromagnetic Compatibility Regulations (S.I. 2016/1091) and fixed installations

DOCUMENT CONTROL

Action	Date	Comment(s)
Version 1.0 released	January 30, 2023	
Version 2.0 released	September 25, 2025	Added ISO/IEC 17065 Scope of Accreditation details for RED Articles 3.3 d, e, f (cybersecurity) Added additional UK optional reference

Note: Please report issues/errors in this document to the NIST TEL MRA Program (mra@nist.gov).